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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/590,782

06/26/2007

Jay J. Farmer

26505-514 NATL

2513

30623

7590

10/27/2010

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EXAMINER

PESELEV, ELLI

ART UNIT

PAPER NUMBER

1623

MAIL DATE

DELIVERY MODE

10/27/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/590,782	FARMER ET AL.	
	Examiner	Art Unit	
	Elli Peshev	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 September 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24 and 32-39 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-24 and 32-39 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>12/12/2006, 8/20/2007, 10/11/2007</u> . | 6) <input type="checkbox"/> Other: _____ |

The abstract of the disclosure is objected to because it has not been presented in the proper domestic form

. Correction is required. See MPEP § 608.01(b).

Claims 1-24 and 32-39 have been examined only insofar as the elected species T is concerned.

Claims 2-4 and 14-16 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim should depend on other claims in the alternative only. See MPEP § 608.01(n).

Claims 1-24 and 32-39 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is not clear at what position the "N-oxide" (claim 1) of the claimed compound is located.

Claims 1-24 and 32-39 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a pharmaceutically acceptable salt of the claimed compound, does not reasonably provide enablement for a prodrug of the claimed compound. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

A conclusion of lack of enablement means that, based on the evidence regarding each of the factors below, the specification, at the time the application was filed, would

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not have taught one skilled in the art how to make and/or use the full scope of the claimed invention.

(A) The Nature of the Invention.

The rejected invention is drawn to a compound that is any prodrug of the structure of formula (I) or the structure of formula (II).

(B) The Breadth of the claims.

The claims are broader than the disclosure. Specifically they encompass any prodrug of the claimed compounds.

(C) The State of the Prior Art.

“Pro-drugs” are commonly known in the art as drugs which are administered in an inactive or less active form, and then metabolized in vivo into an active metabolite.

“Podrugs” prove effect on physicochemical properties of a specific drug such as bioavailability, manufacturability, stability, purification and other performance characteristics of the drug.

(D) The level of predictability in the art.

There is no predictability which specific prodrugs will result in compounds having the desired physicochemical properties.

(E) The amount of direction provided by the inventor.

The inventor has not provided any direction of how to select prodrugs which will result in compounds having the desired properties nor provided any direction for selection, making and using any prodrugs.

(F) The existence of working examples.

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No working examples of any prodrugs have been set forth in the specification.

(G) The quantity of experimentation needed to make or use the invention based on the content of the disclosure.

Because there is no way to predict a priori which specific prodrugs will result in drugs having the desired properties, it would take an enormous amount of trial and error to test various prodrugs on their effect on such properties as bioavailability, stability and other performance characteristics of a drug.

Claims 20-24 and 32-39 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for therapeutic treatment of bacterial infections, does not reasonably provide enablement for prophylactic treatment or prevention or the treatment of any disease state (claim 20), the treatment of any microbial infection (claim 21), the treatment of any proliferating disease (claim 24), the treatment of a viral infection (claim 32), the treatment of an inflammatory disease (claim 33) or the method of treating a disease state caused by a nonsense or missense mutation (claim 35).. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

A conclusion of lack of enablement means that, based on the evidence regarding each of the factors below, the specification, at the time the application was filed, would not have taught one skilled in the art how to use the full scope of the claimed invention without undue experimentation.

(A) The breadth of the claims.

On page 62, lines 41-42 of the specification, it is stated that the terminology “to treat disorders” includes prophylactic treatment. Prophylactic treatment encompasses prevention.

The broadest reasonable interpretation of the term infection merely requires that one microorganism gain entry into the cells of a host. There is no evidence that entry could be prevented.

(B) The state of the prior art.

Erythromycin derivatives are known antibacterial agents.

(C) The amount of direction provided by the inventor.

The inventor has not set forth how to select a host in need of prevention. Also, the inventor has not disclosed whether the prevention is achievable for a period of days, weeks, months, years or whether permanent prevention is achieved.

(D) The existence of working examples.

No working example showing the activity of the claimed compounds have been set forth in the specification. There is no evidence of record showing that the claimed compounds are useful for treating such diseases as viral infections, inflammatory diseases or a disease caused by a nonsense or missense mutation.

(E) The quantity of experimentation needed to use the invention based on the content of the disclosure.

Because there is no way to predict a priori for the treatment of which specific diseases the claimed compounds would be useful, it would take an enormous amount of

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trial and error to test the activities of the various compounds encompassed by the present claims.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-17, 19-24 and 32-39 are rejected under 35 U.S.C. 102(b) as being anticipated by Or et al (WO 99/16779).

Or et al disclose the claimed 3'-N-heterocyclic ring modified erythromycin derivatives useful for treating bacterial infections (pages 2-21). The claimed compounds and methods are anticipated by Or et al.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elli Peselev whose telephone number is (571) 272-0659. The examiner can normally be reached on 8.00-4.30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Jiang can be reached on (571) 272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Elli Peselev
/Elli Peselev/
Primary Examiner, Art Unit 1623